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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 05/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/026,967

Applicant(s)

BEBBINGTON ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 19-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6 and 8-18 is/are rejected.
- 7) ☒ Claim(s) 3,5 and 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-18, drawn to compounds and pharmaceutical composition of formula IIc, classified in class 544, subclass 278, 279, and 284.
 - II. Claims 19-39, drawn to various methods of treatment or use, classified in class 514, subclass 258.1, 260.1, 262.1, 264.11, and 266.23.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of groups I and II are related as product and methods of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the method for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different method of using that product (MPEP § 806.05(h)). In the instant case compounds of group I can also antagonize glycoprotein IbIX, and treat thrombotic disorders as evident by the teaching of **Mederski et. al.** (WO 02/24667).
3. During a telephone conversation with Ms. Karoline Shair on 5-8-03 a provisional election was made without traverse to prosecute the invention of group I, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

5. The disclosure is objected to because of the following informalities:

- a. Some species of formula IIc on page 254-282 (e.g., Examples 82, 85-89, 99-101, etc.) are not analogous to the product obtained from Method A.
- b. Note, many of those species have variable "D" (in R¹) as a heteroaryl, heterocyclyl, or carbocyclyl ring. However, Method A (on page 217) only discloses 3-chloroaniline (i.e., 3-Cl-Phenyl-NH₂) as a starting material for -NH-R¹ (or -NH-D with T as a valence bond). Therefore, there is a discrepancy between Method A and many species of formula IIc. Such a discrepancy causes confusion to one skilled in the art. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 14 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 14 recites the limitation "benzo" in the definition of R^x and R^y . There is insufficient antecedent basis for this limitation in the claim. Claim 14 depends on claim 13, and ultimately on claim 12, which has excluded "benzo" from the ring formed by R^x and R^y .

b. Claim 18 recites the limitation "an additional therapeutic agent", which is unclear if the additional agent is in the same formulation with a compound of formula IIc, or if it is in a separate formulation, but is administered at the same time with a compound of formula IIc.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **Scope of Enablement:** Claims 1, 2, 4, 6, and 8-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the **preparation, and use** of compounds and compositions of formula IIc with ring D as an aryl ring (i.e. phenyl, or substituted phenyl ring), does **not** reasonably provide enablement for the preparation and use of

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compounds and compositions of **formula IIc with ring D as a heteroaryl or heterocyclyl ring**.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The quantity of experimentation necessary;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The breadth of the claims;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The specification only describes Method A for compounds of formula IIc on page 217. Said method only discloses 3-chloro-aniline as the starting material corresponding to -NH-R^1 or -NH-(Ring D) . No other starting material is disclosed for ring D as a heteroaryl or heterocyclyl ring in formula IIc. Thus, following Method A, one can only make compounds of formula IIc with ring D as a phenyl or substituted phenyl ring.

Although the teaching of Mederski et. al. describes the preparation of a few quinazolinyl compounds substituted with indolyl-amine, or pyridyl-amine at the second position, said compounds differ from the claimed compounds by not having pyrazolyl-amine at the fourth

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position. Therefore, the skilled chemist cannot assume the same course of reaction to obtain the claimed compounds. Furthermore, said teaching does not disclose how one can obtain or prepare the starting materials of indolyl-amine or pyridyl-amine. Thus, the skilled chemist cannot rely on the teaching of Mederski et. al. to remedy the enablement deficiency of the instant disclosure.

Thus, with the unpredictable nature of the art, and limited guidance provided, one skilled in the art will have to carry out undue experimentation to make and use compounds and compositions of formula IIc with ring D as a heteroaryl or heterocyclyl ring.

Claim Objections

8. **Improper dependent claims:** Claims 3, 5, and 7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Said claims depend on claims 2, 4, and 6 (respectively), but they have the exact same scope as that of claims 2, 4, and 6, and thus do not further limit claims 2, 4, and 6.

Information Disclosure Statement

9. The IDS of 9-18-02, and 9-27-02 have been considered. The most relevant reference is that of Mederski et. al. (WO'667), which only provides a generic teaching for the claimed formula IIc without an express motivation to select compounds of the claimed formula IIc. Thus, no prima facie case of obviousness can be established.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Tamthom N. Truong
Examiner
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May 17, 2003